EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Competitiveness in the Pharmaceuticals Industry and Biotechnology

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MANDATE ADDRESSED TO CEN, CENELEC AND ETSI FOR THE ELABORATION OF A PROGRAMME OF STANDARDS TO TAKE INTO ACCOUNT THE SPECIFIC PROPERTIES OF NANOTECHNOLOGY AND NANOMATERIALS

1. SCOPE

This mandate concerns the elaboration of a programme of standardisation in the area of NANOTECHNOLOGIES AND NANOMATERIALS. It also relates to the review of already existing standards so as to take into account the specific features of nanotechnology and nanomaterials/nanoproducts due to their specific chemical, physical and biological properties and ways of interaction.

2. JUSTIFICATION

2.1 Rationale

Nanotechnologies are a rapidly developing field of science, technology and innovation. It involves the development and manufacture of materials in the nanometre size range and includes the production and use of nanoparticles. Nanosciences and nanotechnologies aim at understanding and controlling the fundamental structure and behaviour of matter at the level of atoms and molecules. These emerging technologies are going to lead to the identification of new phenomena and properties which are expected to open up new avenues of applications and may also be the source of concerns with regard to risks caused by their specific properties.

Nanotechnology is an enabling technology. Currently, the full scope of applications cannot be determined. However, major implications are expected in the following non-exhaustive list of fields:

- medical applications
- information and communication technologies
- energy production and storage
- materials science/chemical engineering
- manufacturing
- food, cosmetics, water and environmental
- security

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It is assumed that nanotechnologies will become major drivers of change. It is a generally shared notion that a thriving high-tech industry is a key to Europe's economic and political viability due to its direct and indirect effect (e.g. spill-over effects). Consequently, it is of utmost importance to translate European excellence in nanosciences into safe and commercially marketable products and processes. Nanotechnologies are emerging as one of the most promising and rapidly expanding fields of R&D to give new impetus to the dynamic knowledge-based objectives of the Lisbon process. It is crucial that a favourable environment for innovation, which allows in particular small and medium sized enterprise (SMEs) to apply and commercially exploit these technologies, is created.

It also has to be underlined that standards play a role for regulatory compliance, in particular in areas where regulation requires a risk assessment and risk management approach, compliance with which can be demonstrated by standards.

Although this area of technology has progressed fast with many commercial products already in use, the full scale of their properties still remains unknown. It is general accepted that, to date, the full implications of these new technologies have not been ascertained yet, neither with regard to safety, health and the environment nor to the economic effects due to its commercialisation. In any case ethical principles must be adhered to and potential health, safety or environmental impacts scientifically studied.

2.2 Political Context

Given the enormous potential of nanotechnologies for competitiveness of industry and society at large, it has to be ensured that nanotechnology is developed in a safe and responsible manner. At different levels, policies to this end are being undertaken.

The European Commission has set out its "safe, integrated and responsible» approach towards nanotechnologies in two Communications "Towards a European Strategy for Nanotechnology" and the "N&N Action Plan for Europe 2005-2009". (COM(2004) 338 final and COM(2005) 243 final).

On 28 September 2006, the European Parliament has endorsed this approach in its Resolution on Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009, highlighting the role of standardisation in this process.

Commission Working Groups are currently examining, or will do so, the need as to whether current regulation and supporting documents, such as regulatory guidance, cover risks in relation to nanotechnologies and nanomaterials in an appropriate way.

The EU's the Scientific Committee for Emerging and Newly Identified Risks has adopted on 10 March 2006 an opinion on "The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies", [1]and is currently elaborating a new opinion regarding the "appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing (chemical) substances for assessing the risks of nanomaterials." This opinion is expected in the course of 2007. This opinion is expected to provide concrete suggestions for improvement of the methodology where current risk assessment methodology may be improved for assessment of nanomaterials, and taking into account the practical limitations of

[1] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf

the information available for risk assessments, provide. The Commission has asked to distinguish between

- improvements that can be made based on current knowledge,
- improvements that would require specific information on the nanomaterials, and
- improvements that will require scientific research before they can be implemented.

At the international level, activities are ongoing within the framework of the OECD, which is supported by the Commission. Relevant work is carried out particularly in the Chemicals Committee and the Working Party on manufactured nanomaterials, which was confirmed by the OECD Council in September 2006.

OECD remit will focus on priority setting in order to promote

- cooperation on health and environmental safety related aspects of manufactured nanomaterials and
- understanding of the health, environmental and exposure implications of manufactured nanomaterials.

The Working Party will also ensure a proper coordination and cooperation, in particular with other relevant international organisations, especially those of the Inter-Organisation Programme for the Sound Management of Chemicals (e.g. UNEP, ILO, FAO, WHO, UNIDO and UNITAR) and possibly UNESCO, standardisation organisations (e.g. ISO and IUPAC), and nomenclature organisations (e.g. CAS).

European standards bodies have also taken up the issues related to nanotechnology/nanomaterials in their work. Among other activities the European Committee for Standardisation has already set up the Technical Committee 352 (TC 352) for standardisation in the field of nanotechnologies, and a “Strategy for European Standardisation for Nanotechnologies” was presented to the CEN/BT in June 2005.

Furthermore, ISO has also established a Technical Committee dealing with nanotech-related issues, (terminology and nomenclature, measurement and characterization, health, safety and environmental issues). Cooperation between ISO and CEN is ensured through the Vienna Agreement. Furthermore ISO is currently defining its work programme. Specific issues that have been identified concern nomenclature for nanoparticles, occupational good practice and endotoxicology.

The IEC has started standardisation on nanotechnology in relation to electrical and electro technical products and systems, European input to which will be ensured through CENELEC.

It is of utmost importance that these activities take place in a consistent and coordinated way, in a joint approach agreed by major trading partners.

In the light of current activities and knowledge, and without prejudice to specific sectoral needs, priorities for standardisation are:

- the classification, terminology and nomenclature of nanomaterials;
- metrology including sampling and measurements methods

Furthermore, account should be taken of activities concerning the characterization (including procedures and materials for calibration) of nanomaterials.

The results of these activities are useful for future applications in the areas of workplace, environmental exposures and safety.

3. DESCRIPTION OF THE MANDATE

In order to promote the development and application of nanotechnologies and nanomaterials, CEN, CENELEC and ETSI are invited to execute the following tasks, taking full account of and building upon – as appropriate - the "Strategy for European Standardisation for Nanotechnologies", prepared by CEN/BT/WG 166 Nanotechnologies and submitted to the CEN/BT in June 2005." and the "Report of the 2nd meeting of CEN/TC 352, Document CEN/TC 352N38":

- To take stock of current standardisation relevant to nanotechnologies and nanomaterials (e.g. cosmetics, medical devices assessment, personal protective equipment, air quality, and food contact etc.) which may need a revision in the light of risks associated with nanotechnologies and nanomaterials;

- Identify the need for new standards;

- Identify the need to develop standardisation documents other than standards in relation to the above mentioned priority areas;

- Identify the availability of stakeholders in the EEA with a view to associate them when necessary in the standardisation process.

In order to respond rapidly to the different activities in this very fast moving area, optimal and effective consideration should be made of the so called 'CEN/CENELEC workshop agreements' and other similar documents.

CEN, CENELEC and ETSI are requested to take into account on-going pre-normative research and development (including relevant work done by relevant stakeholders, industry, in national as well as international fora and the Commission's Framework Programmes for research, i.e. FP6 and FP7) and co-ordinate their activities in order to avoid any duplication of work.

Moreover, they should also establish and/or build upon existing appropriate links for the above described tasks with relevant European Technology Platforms (e.g. Sustainable Chemistry (SusChem) especially for metrology and characterisation of nanomaterials; Industrial Safety (ETPIS) for workplace and environmental safety aspects (especially exposure aspects); nanoelectronics for specific application/use aspects in electronics; and nanomedicine for medical applications such as drug delivery, etc.) to ensure a coordinated and fast progress of their tasks.

Standardisation activities should be consistent with work carried out and priorities set by OECD.

European standardisation efforts will preferably be elaborated in cooperation with the international standards bodies.

4. EXECUTION OF THE MANDATE

The Commission hereby asks CEN, CENELEC and ETSI to fulfil the tasks as described above, while taking into account the rationale of this mandate stated in the justification.

CEN, CENELEC and ETSI should consider setting up a joint working structure to execute the mandate, keep close contacts with the Commission and ensure that their activities are co-ordinated in a way to create a consistent and coherent framework at the international level, notably with regard to ISO, IEC and OECD activities.

The report will be provided within 6 months after the acceptance of the mandate, identifying

- the programme of standardisation items,,
- the legal status of foreseen standardisation documents and
- an assessment of the feasibility of having standardisation work carried out at the international level, and
- a draft roadmap of the progress of standardisation activities considered necessary.

5. BODIES TO BE ASSOCIATED

The execution of the mandate should be undertaken in cooperation with the widest possible range of interested groups: International standards bodies (ISO, IEC, and ITU), The Joint Research Centre of the European Commission, OECD Activities as well as research institutes, and the different relevant technology platforms (see section 4 of this mandate).

As appropriate, CEN, CENELEC and ETSI will invite the standardisation stakeholders representing consumers' interests (ANEC), environmental protection (ECOS), workers (ETUI-REHS) and SMEs (NORMAPME) to take part in the development of the programme.